Boston Scientific

PATIENT INFORMATION BOOKLET

Wingspan™ Stent System with Gateway PTA Balloon Catheter

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Humanitarian Device. The Wingspan™ Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system.

Indications, contraindications, warnings, and instructions for use can be found in the product labeling (*Instructions for Use)* supplied with each Wingspan™ Stent System.

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Definitions

Here are definitions for some of the medical words used in this Patient Information Booklet. There may be other words used in the Booklet that are not defined here. If you do not know what they mean, ask your doctor.

Aneurysm – A bubble-like swelling in the wall of an **artery**.
Angioplasty – A procedure in which a balloon is used to open blocked vessels. Also known as percutaneous transluminal angioplasty (PTA).
Artery – A blood vessel that carries blood away from the heart and to important organs like the brain.
Atherosclerosis – A disease that causes an **artery** wall to thicken or harden. When this disease affects the coronary arteries, it can cause a heart attack. When this disease affects the **neurovascular arteries**, it can cause a **stroke**.
Balloon Angioplasty – Opening the blocked **artery** by using a balloon **catheter** that is inflated inside the vessel.
Catheter – A long, thin, flexible plastic tube used to provide access to parts of the body through the arteries.
Contrast Media (Dye) – A liquid dye injected into blood vessels during some X-ray procedures to help see the blood vessels.
Introducer Sheath – A short, plastic tube that is inserted into the body to provide an access point (groin). It allows insertion of other instruments into the **artery**.
Intracranial – Inside the skull.
Ischemic – Caused by a lack of blood due to a blockage in a blood vessel.
Lesion – A narrow section in an **artery** caused by **atherosclerosis**.
Lumen – The inner channel of a vessel.
Magnetic Resonance Imaging (MRI) – A special technique similar to an X-ray used to see pictures of internal structures, such as arteries, the brain, or the heart.
Neurovascular Artery or Arteries – Arteries in the brain that supply blood containing oxygen and nutrients to the brain.
Plaque – A buildup of cholesterol, fatty deposits, calcium, and collagen in a vessel. This can cause blockages in the blood vessel.
Restenosis – Repeat blockage or narrowing of a vessel that has already been treated.
Stenosis – A narrowing of or blockage in an **artery** caused by **atherosclerosis**.
Stent – A small, metal mesh tube used to support the walls of an **artery**.
Stroke – A blockage in an **artery** of the brain that can stop the supply of blood. A **stroke** can cause parts of the body to be paralyzed. A **stroke** can even cause death.
Vessel Recoil – Arteries that are stretched during an **angioplasty** procedure may "shrink back" after they are stretched.

What is the Purpose of This Booklet?

Your doctor believes that the best treatment for the disease in your brain includes the use of a device called the Wingspan Stent System. This Patient Information Booklet was created to help you make an informed decision about this treatment. Please read it carefully. Make a list of questions and concerns and discuss them with your doctor before agreeing to the treatment. We have included a ***Definitions*** section at the front of the booklet that provides definitions for the words in bold print.

What is an Intracranial Lesion?

An **intracranial lesion** is a caused by **atherosclerosis**, and affects the **neurovascular arteries** that are in the brain. These arteries supply blood with oxygen and other nutrients to the brain to make it function properly. An **intracranial lesion** occurs when the inner walls of the arteries thicken due to a buildup of cholesterol, fatty deposits, calcium, and other elements. This material is known as **plaque**. As **plaque** forms, the vessel narrows. When the vessel narrows (for example, with physical effort or mental stress), blood flow through the vessel is reduced so less oxygen and other nutrients reach the brain. This reduced blood flow may cause mild to severe headaches or other symptoms. Complete blockage (no blood flow) of a **neurovascular artery** can result in a **stroke**.

Anyone who has symptoms of severe headaches should see a doctor promptly.

Over 700,000 Americans suffer from **stroke** each year. Of these **strokes**, 468,000 are caused by **ischemic** disease. However, treatment options for **strokes** that are caused by **intracranial lesions** have improved in recent years. Many **stroke** patients are now able to benefit from a new treatment option.

Who is at Risk?

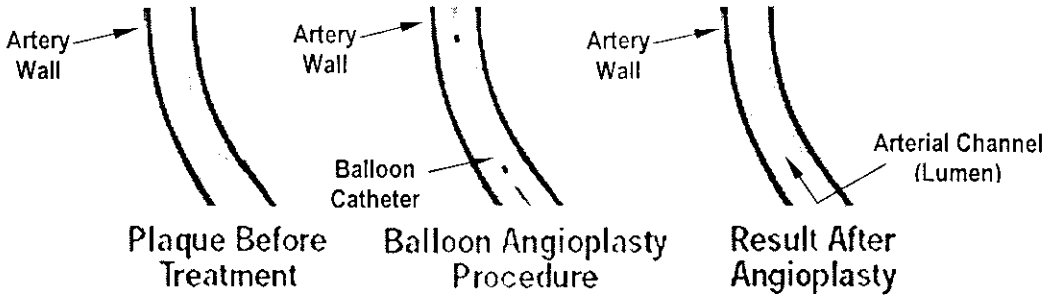
Several factors increase the risk of getting **atherosclerosis** in the **neurovascular arteries**. These factors include a history of smoking, high cholesterol, diabetes, high blood pressure, being overweight, and a family history of **stroke** or heart disease.

What is the Treatment for Intracranial Lesions?

Intracranial lesions may be treated in several ways. The treatment that your doctor recommends to you will depend on how severe your condition is. Medical treatments may include medications, **angioplasty**, or **stent** placement.

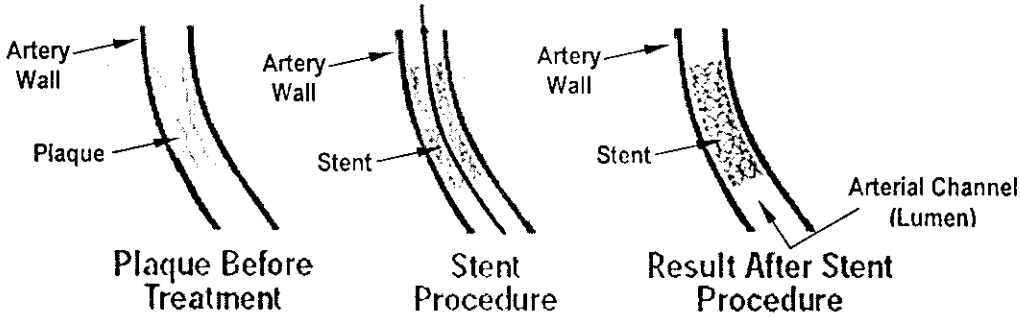
Angioplasty

Angioplasty is a non-surgical treatment of the **neurovascular arteries**. It is performed in the hospital to open blocked arteries. A thin tube known as a **catheter** is inserted through the groin and is threaded through a major blood vessel to the site of the blockage. PTA can be performed with a balloon alone, or can involve inserting a neurovascular **stent**.



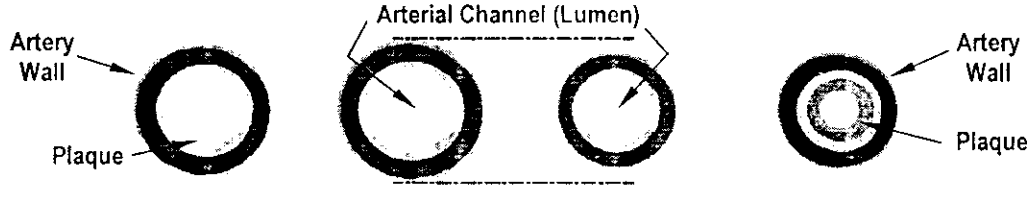
Neurovascular Stents

Neurovascular **stents** are devices that can help to reduce the risk of recurrent blockage or of narrowing after an **angioplasty** procedure. **Stents** are small expandable metal tubes that are implanted in a vessel. They expand to fit the size, shape, and bend of the vessel wall and prop it open to help prevent future blockages. Once it is in place, the **stent** will remain in your **artery**. Over time, the **artery** wall will heal around the **stent** as it continues to support the vessel.



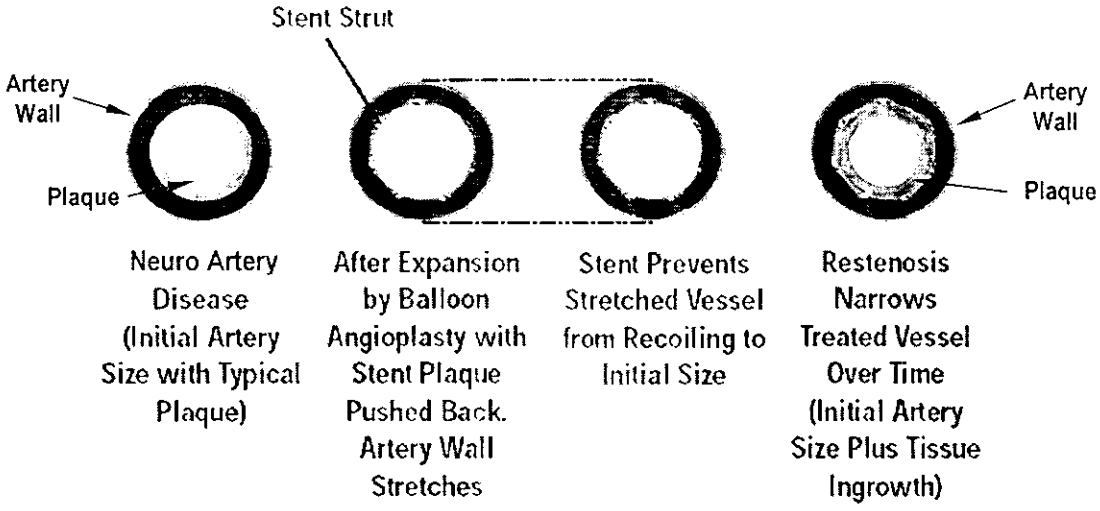
What is Restenosis?

Some patients who undergo **balloon angioplasty** treatment will have a renarrowing of the **artery**, or **restenosis**, in the area that was treated. Many patients who do not receive a **stent** within the first six months after their **balloon angioplasty** procedure may have **restenosis**. The renarrowing can be caused by a combination of things including **vessel recoil** and tissue growth in the treated area.



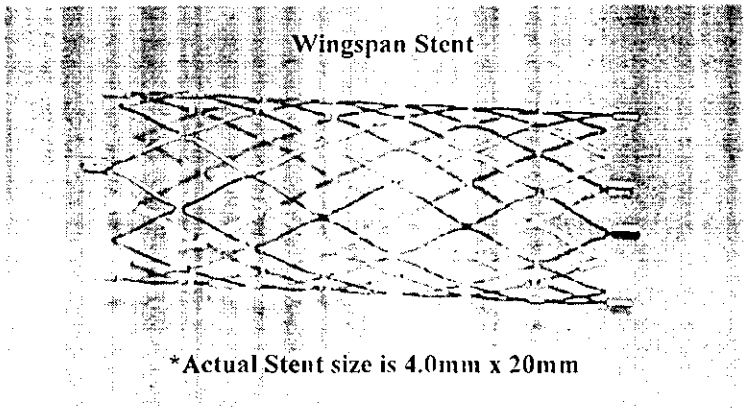
Although **stents** have proven to reduce **restenosis** compared to **balloon angioplasty** alone, **restenosis** still may occur in patients who receive **stents**. Unlike **restenosis** after **balloon**

angioplasty, **restenosis** in a **stent** (in-stent **restenosis**) is not normally caused by **vessel recoil**. Instead, in-stent **restenosis** is mainly caused by tissue growth around the **stent**.

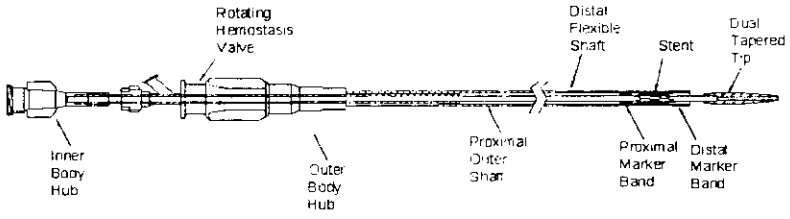


What is the Wingspan Stent System™ with Gateway™ PTA Balloon Catheter?

The Wingspan Stent System with Gateway PTA Balloon Catheter consists of a Wingspan Stent, a Wingspan Delivery System, and a Gateway PTA Balloon Catheter. The Balloon Catheter is temporarily put into the **artery** to open the blockage before the **Stent** is inserted. The **Stent** is a permanent implant that is placed across the blockage. It is a tiny mesh tube that is made from a metal alloy called nitinol, which is a blend of nickel and titanium metals.



The Wingspan Delivery System consists of a **catheter** that is used to thread the **Stent** through your **artery** to the blockage. The **Stent** helps to keep the **artery** open.



Who is Not Eligible for the Wingspan Stent System?

The Wingspan Stent System cannot be used if you cannot take blood thinning drugs that make your blood less likely to clot.

What are Warnings and Precautions to Consider?

The Wingspan Stent has been shown to be compatible with **magnetic resonance imaging** (MRI). This means that the **Stent** can be used in certain MRI machines without causing harm to you. This is very important to know if in the future you need an MRI scan for any part of your body. Before you have an MRI scan, or for questions about your Wingspan Stent or procedure, please contact the implanting physician or show the Wingspan Stent System card given to you by the implanting doctor to the person performing the MRI scan. The Wingspan Stent System has been shown to be MRI compatible in MRI systems operating at field strengths of 3.0 Tesla or less.

Do not undergo this procedure if you are under the age of 18 years old. The procedure has not been performed in patients who are below the age of 18, and it is unknown what may happen.

What are the Potential Complications?

Potential adverse events, which may be linked to **balloon angioplasty** and neurovascular **stent** insertion include:

- air, tissue, or clots which can block the vessel (emboli)
- allergic reaction to the **contrast media** (could include kidney failure)
- allergic reaction to the metal used to make the **stent** (nickel, titanium, or platinum)
- **aneurysm**
- bleeding that would require a blood transfusion
- bruising which resides on a blood vessel (pseudo-**aneurysm**)
- headache or discomfort
- collection of blood in the lining of the heart
- vessel spasm (closure)
- death
- high or low blood pressure
- poor supply of blood to the brain
- infection or pain at the access site

- injury or tearing of blood vessel
- irregular heart beat (arrhythmia)
- movement of the **Stent** after insertion
- blockage of the **Stent** with blood clots
- **restenosis** in the treated vessel
- side effects due to **contrast media** or heparin
- **stroke** or other neurological events
- total blockage or closure of the vessel
- abnormal connection between vein and **artery** (arterio-venous fistula)
- vessel trauma requiring medical treatment
- worsening of symptoms

What Were the Clinical Study Results?

The safety and probable benefit of the Wingspan Stent was studied in the Wingspan Stent trial that included 45 patients. All patients were followed for 6 months. The study results showed that patients who received a Wingspan Stent had improved blood flow through the neurovascular **artery** treated. One out of 45 patients in this trial needed retreatment with a **stent**, 4 out of 45 patients had a **stroke**, and 1 patient, who had a stroke, out of 45 patients died within 6 months of having the procedure.

Are There Any Alternative Practices and Procedures?

Treatment of patients with **neurovascular artery** disease, including in-stent **restenosis** or **stroke**, may include exercise, diet, drug therapy, **angioplasty**, or stenting.

How Do You Prepare for the Angioplasty and Stent Placement Procedure?

Your doctor will instruct you on how to prepare for the **angioplasty** and **stent** insertion procedure prior to being admitted to the hospital. Your doctor may ask you to take aspirin and other prescribed medications for several days before the procedure. This is done to "thin" the blood to prevent blood clots from forming during the procedure. It is important to tell your doctor if you cannot take aspirin or if you have a history of bleeding problems. Your doctor also needs to know if you are taking any other medications, have drug allergies, or are allergic to any metals or plastics.

What Happens During the Angioplasty and Stent Placement Procedure?

Your **angioplasty** and **stent** implant procedure will be performed in a specially equipped area of the hospital. You will have to lie flat on your back during the procedure. You may either be awake or asleep. If you stay awake, this will allow you to follow your doctor's instructions or answer questions that you are asked. Your groin will be shaved and cleaned with antiseptic, and you will be given a local anesthetic to numb the area.

Your doctor will place an **introducer sheath** in your groin to gain access to the **artery**. The sheath allows the doctor to slide a small guide **catheter** up to the entrance of the blocked **artery**. Through the guide **catheter**, **contrast media** will be injected to help the doctor see the blocked

arteries on the X-ray machine. A finer guidewire is then advanced through the guide **catheter** to the **stenosis**, or blockage, in the diseased **artery**. This provides the "railway track" that carries all the tools necessary for the procedure.

Using the guide **catheter**, a balloon **catheter** is placed in the blocked area of the **artery**. Once in place, the balloon is inflated, which compresses the **plaque** and widens the **artery**. At this time you may have some discomfort. Although this is normal, let your doctor know if you are having any pain.

After the **artery** has been widened, your doctor will insert the Wingspan Stent, mounted inside a Delivery Catheter, into the **artery** where the balloon was inflated. Your doctor will insert the **Stent**. The **Stent** will expand by itself to the size and contours of the inner wall of your **artery**. Once in place, the Wingspan Stent will stay as a permanent implant in your **artery**.

What Happens After the Procedure?

After the procedure

After the **Stent** is implanted, you will be moved to a neurology ward for a short time where you can be observed closely as you begin to recover. On average, your hospital stay may last one to three days before you are discharged.

Activity

- Follow your doctor's guidelines.
- Return to normal activities slowly, pacing your return to your activities as you feel better. Check with your doctor about strenuous activities.
- Let your doctor know about any changes in lifestyle you make during your recovery time.
- Report side effects from medications to your doctor
- Keep taking your medications unless you are asked to stop by your doctor
- Keep all follow-up appointments, including laboratory blood testing.
- Carry your Wingspan Patient Information Card (shown in the back of this booklet) at all times. If you receive dental or medical care or report to an emergency room/center, show your Wingspan Patient Information Card.

Medications

Your doctor may prescribe a number of medications to thin the blood and prevent blood clots from forming and sticking to the surface of the **Stent**. You will be asked to take a small daily dose of aspirin indefinitely. In addition to aspirin, you will also need to take drug prescriptions for a period of several months. It is extremely important to take your drug prescriptions.

Follow-Up Examinations

You will need to see the doctor who implanted your **Stent** for routine follow-up examinations. During these visits, your doctor will check your progress and assess your drug prescriptions. Your doctor will also check to see how the **Stent** is working for you. Tell your doctor right away if you start having any of the following symptoms:

- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- Sudden confusion, trouble speaking or understanding

- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, loss of balance or coordination
- Sudden, severe headache with no known cause

Frequently Asked Questions

Can the Stent move or rust?

Once your doctor inserts the **Stent**, it does not move on its own. It is manufactured so that it will not rust.

Can I walk through metal detectors with a Stent?

Yes, without any fear of setting them off.

How soon can I go back to work?

The majority of people return to work within a few days after the procedure.

What if I still get symptoms?

If you start having symptoms, immediately tell either your doctor or the center where the procedure was performed.

Can I have MRI or scanner testing with a Stent?

Before you have a **magnetic resonance imaging** (MRI) scan, or for questions regarding your Wingspan Stent System or procedure, please contact the implanting physician. The Wingspan Stent System has been shown to be MRI compatible in MRI systems operating at field strengths of 3.0 Tesla or less. Your **Stent** should not move during an MRI scan. Prior to undergoing these examinations, inform your doctor that you have a **Stent**.

Can I play sports?

Your doctor will tell you if you can join in physical activities or play sports. Your doctor can also tell you what sports or activities this includes and when you may start them.

What should I change in my diet?

Your doctor may prescribe a low-fat, low-cholesterol diet to help lower the levels of fat in your blood. This may also lower your risk of future **stroke**.

Patient Information Card

Below is a sample of a Wingspan Patient Information Card. Your doctor will fill out a card like this for you after the treatment. Make sure your doctor gives this card to you before you leave the hospital. You should keep this card with you at all times. It is very important to show this card to other doctors that you go to in the future. The card will explain that you have a **Stent** in your brain.

Card Outside

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Wingspan™ Stent System

PLEASE CARRY YOUR CARD AT ALL TIMES

MRI Compatibility

Before you have a Magnetic Resonance Imaging (MRI) scan, or for questions regarding your Wingspan Stent System or procedure, please contact the implanting physician. The Wingspan™ Stent System has been shown to be MRI compatible in MRI systems operating at field strengths of 3.0 Tesla or less.

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Card Inside

Patient Name
Patient Phone Number
Date of Implant
Stent Location
Stent Lot Number
Number of Stents Implanted
Implanting Physician Name
Physician Telephone Number

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